ROTATION DESCRIPTION

ROTATION TITLE
Investigational Drug Services (IDS) (PGY1)

PURPOSE
The purpose of this IDS rotation is to allow the resident to develop skills in managing the pharmaceutical requirements of a clinical research and finding ways to fulfill those objectives within the hospital's setting, often delegating duties to the medical center's pharmacies. In doing so, the resident will develop a more thorough understanding of the conduct and challenges in carrying out clinical trials from study initiation to termination, the applicable regulations and the protection of human subjects.

LEARNING EXPERIENCE DESCRIPTION
This rotation provides interested residents an opportunity to learn about and work in a unique field of pharmacy. The Investigational Drug Services (IDS) manages the investigational agents for MUSC's inpatient and outpatient clinical trials. The role of the IDS is to oversee the acquisition, accountability, storage, security, packaging, labeling and distribution of study drugs.

A typical day in the IDS is driven by patient need but is structured as follows. The preparation and dispensation of oral and intravenous study medications is highly concentrated in the morning, coinciding with clinics. Dispensing continues throughout the day in smaller volumes. Afternoons are typically consumed with administrative duties such as review of protocols, setting up new studies, inventory management and meetings. Appointments for monitors and auditors begin at 11 am and continue throughout the day. The resident meets with the preceptor at the end of each day to discuss the current studies, the role of the resident and the resident's projects. The resident should provide prompt feedback to the preceptor of topics not properly explained to him/her and areas of improvement for the preceptor/IDS staff.

LEARNING EXPERIENCE ACTIVITIES
- Review and summarize clinical protocols
  (R5.1.6; R6.1.2; R6.1.3; E2.3.1)

- Create spreadsheets and drug accountability logs for tracking the use of investigational agents
  (R2.12.3; E7.5.2)

- Prepare and set-up IRB-approved studies to be ready for the acquisition, accountability, storage, security, packaging, labeling and distribution of study drugs.
  (R3.2.4)

- Create drug description of study number, drug name, strength, how supplied, storage, route of administration, dose, dilution instructions if intravenous, administration instructions and any special instructions for the IDS information

sheet and for pharmacy information systems to use to create pharmacy labels and Medication Administration Records.
(R6.1.2; R6.1.3; E2.3.1; E7.5.1)

- Actively participate in protocol-specific pre-site and site-initiation visits.
(R2.1.1; E2.3.1)

- Provide in-service education to IDS staff, inpatient pharmacy staff, nursing and research staff.
(R2.1.1; R2.11.1; R2.11.2; R5.1.1; R5.1.2; R5.1.6)

- Assist in the dispensing of investigational agents according to protocol-specific requirements and standardized IDS procedures.
(R1.3.3; R1.3.4; R2.4.1; E2.3.1)

- Review physician's orders by verifying accuracy and appropriateness using patient-specific information, the protocol, the Medical Center's Policy on Medication Orders for inpatient and clinic orders and SC Law on outpatient prescriptions.
(R1.3.1; R1.3.2; R1.3.4; E7.5.1)

- Assess and evaluate applicable laboratory reports to determine course of treatment and changes in dose or drug regimen.
(R2.4.1; R2.10.1; R6.1.3; E7.5.1)

- Demonstrate an understanding of the evolving need for the protection of human subjects, the barriers, and the resulting handicaps and apply this knowledge to IDS and MUSC.
(R2.4.2; R3.1.3)

- Become familiar with the areas of the Distribution Center and the roles the independent services provide.
(R2.1.1; E2.2.1)

- Assure departmental compliance with institutional policies, accreditation, legal, regulatory, and safety requirements.
(E2.3.1; R3.2.2)

- Provide concise, applicable and timely responses to requests for drug information from your preceptor, IDS staff, study coordinators, monitors and other study-related staff.
(R1.5.1; R1.5.2; R1.5.3; R1.5.5; R1.5.6)

- Evaluate the process for providing pricing guidelines and negotiating and developing estimates for starting new studies.
(R3.2.3)

REQUIREMENTS OF LEARNING EXPERIENCE

Required hours
8:00 AM to 5:00 PM
The above times may vary according to IDS schedule/needs

Required meetings
Daily meetings with preceptor
Weekly meetings with preceptor
Monthly Distribution Center Staff Meetings
Monthly Pharmacy Department Staff Meetings
Monthly IRB Meeting, 1st Tuesday of the Month from 12pm to 2pm
Pre-Site and Site-Initiation Visits that may occur during the month

Required presentations
1-2 presentations to the IDS staff on a study-related topic as decided by the resident and preceptor

Required readings
- MUSC Investigational Drug Services Policy and Procedures
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines On Good Clinical Practice
- Collaborative Institutional Training Initiative (CITI) on-line course, www.citiprogram.org
- Protecting Human Research Participants, NIH Office of Extramural Research, http://phrp.nihtraining.com
- Current protocols managed by the IDS during time of rotation assigned on the first day and as they are received in the IDS

ROTATION PRECEPTOR(S)
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METHOD OF EVALUATION
Evaluation of residents will be based on the learning experience objectives outlined by the Residency Program Director (RPD). The RPD will identify the specific goals and objectives on which the resident will be evaluated (available in E-Value). The preceptor and resident will review the resident's customized plan and the learning experience introduction document on the first day of rotation. Feedback will include, but not be limited to, verbal and written mid-point and end of rotation evaluations.

Appendix

Topics to be Reviewed during the IDS Rotation

- Protection of Research Subjects
- Confidentiality with Special Emphasis on Research Subjects and Vulnerable Populations
- FDA, State, Joint Commission and Hospital Requirements on Drug Dispensing as applicable to the IDS
- IRB Review Process
- Randomization
- Interactive Voice Response System